

## REMARKS

Claims 11-14 are pending in the subject application. Claims 1-10 have been canceled. Claim 11 has been amended to clarify the claimed subject matter. No new matter has been added. Entry of this Amendment and reconsideration of the application are respectfully requested.

### **I. Priority**

On page 2, section 2 of the Office Action, the Examiner states that "Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120" (page 2, section 2 of the Office Action). The Examiner further states that the first sentence of the application "must contain a specific reference to the prior application(s) (page 2, section 2 of the Office Action). Paragraph [0001] of the subject application has been amended to read that the subject application "is a division of U.S. application Serial No. 10/414,852, now U.S. Patent No. 6,723,729 B1." Accordingly, the subject application now complies with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120.

### **II. Indefiniteness Rejection under 35 U.S.C § 112, Second Paragraph**

The Examiner has rejected claims 11-14 under 35 U.S.C § 112, second paragraph being allegedly indefinite. The Examiner alleges "[i]n independent claim 11, the term --total-- is indefinite since its meaning or actual intent is not clear" (page 2, section 5 of the Office Action). Claim 11 has been amended to delete the term "total." Accordingly, Applicant respectfully submits that claim 11 is not indefinite, and requests that the rejection of claims 11-14 under 35 U.S.C § 112, second paragraph be withdrawn.

### **III. Obviousness Rejections under 35 U.S.C § 103(a)**

The Examiner has rejected claims 11-14 under 35 U.S.C § 103(a) as being allegedly obvious over U.S. Patent No. 6,476,043 B1 to Toutain et al. ("Toutain") or U.S. Patent No. 6,545,010 B2 to Bissery ("Bissery") for the reasons set forth on page 3, section 8 to page 5, section 9 of the Office Action. Applicant respectfully traverses these rejections.

**1. Claims 11-14 are not Obvious over Toutain**

Toutain is directed to “protection against gastrointestinal side effects by “administration of a sodium chloride solution simultaneously with the administration of a camptothecin derivative” (col. 2., lines 32-35 and 39-41). Toutain teaches that the sodium chloride solution “can also comprise other agents, such as in particular sweeteners or flavourings” (col. 2., lines 56-57). Toutain also teaches that compositions for intravenous administration “can also contain adjuvants” (col. 3, lines 7-8) while compositions for oral administration can contain “one or more inert diluents or adjuvants” (col. 3, line 19). The Examiner states that “Toutain discloses use of camptothecin derivatives, with reduced gastrointestinal toxicity.” The Examiner alleges that “Toutain teaches the utility of irinotecan for treating cancer ... It is also well established in the prior art to combine the main therapeutic compound with other compounds in order to produce a synergistic effect or reduce its side effects as combined by Toutain.” The Examiner concedes that Toutain “does not mention detectable amount of 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate in the composition.” However, the Examiner contends that “in the absence of some unexpected results of superior activity or reduced side effects by the instant combination over the prior art, it would have been obvious to one skilled in the art to prepare the instant composition without losing its therapeutic utility for treating cancer.” Applicant respectfully disagrees.

“To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981 (Fed. Cir. CCPA 1974)).

As discussed above and as conceded by the Examiner, Toutain does **not** teach or even suggest a composition containing 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate, let alone a composition comprising irinotecan and said 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate. Accordingly, one of skill in the art would find no motivation to modify the camptothecin derivative composition taught by Toutain and arrive at a composition “comprising irinotecan and/or at least one salt thereof in a therapeutically effective amount and 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate and/or at least one salt thereof in a detectable amount” as recited in independent claim 11 of the subject application. Therefore, Applicant respectfully submits that claims 11-

14 are not obvious over Toutain, and requests that the rejection of claims 11-14 under 35 U.S.C § 103(a) be withdrawn.

**2. Claims 11-14 are not Obvious over Bissery**

Bissery is directed to a pharmaceutical composition containing camptothecin (or a camptothecin derivative) and a platin derivative. The Examiner alleges that “Bissery teaches the utility of irinotecan for treating cancer ... It is also well established in the prior art to combine the main therapeutic compound with other compounds in order to produce a synergistic effect or reduce its side effects as combined by Bissery.” The Examiner concedes that Bissery “does not mention detectable amount of 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate in the composition.” However, the Examiner contends that “in the absence of some unexpected results of superior activity or reduced side effects by the instant combination over the prior art, it would have been obvious to one skilled in the art to prepare the instant composition without losing its therapeutic utility for treating cancer.” Applicant respectfully disagrees.

As discussed above and as conceded by the Examiner, Bissery does not teach or even suggest a composition containing 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate, let alone a composition comprising irinotecan and said 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate. Accordingly, one of skill in the art would find no motivation to modify the camptothecin/platinum anti-tumor composition taught by Bissery and arrive at a composition “comprising irinotecan and/or at least one salt thereof in a therapeutically effective amount and 4-amino-3-propionylphenyl-1,4'- bipiperidine-1'-carboxylate and/or at least one salt thereof in a detectable amount” as recited in independent claim 11 of the subject application. Therefore, Applicant respectfully submits that claims 11-14 are not obvious over Bissery, and requests that the rejection of claims 11-14 under 35 U.S.C § 103(a) be withdrawn.

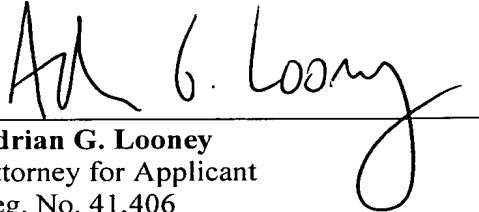
**IV. Conclusion**

In view of the above amendments and remarks, Applicant submits that the present claims are now in condition for allowance. Applicant does not believe any additional fee(s) are due in connection with this Amendment . However, if any additional fee(s) is due, Applicant's attorney authorizes payment from deposit account number 16-1445 or the credit of any overpayment to the aforementioned deposit account.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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**Adrian G. Looney**  
Attorney for Applicant  
Reg. No. 41,406

Pfizer Inc  
Patent Department, 5th Fl.  
150 East 42nd Street  
New York, NY 10017-5612  
(212) 733-1038